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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

THANH, LOAN H

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 03/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/406,473

Applicant(s)

PACETTI, STEPHEN D.

Examiner

LoAn H Thanh

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) 11-47 and 61-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 48-60, 64 and 65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Response to Amendment

The 35 USC §112, 2nd paragraph rejection is being maintained.

With respect to the election/restriction of claims 11-15, the Examiner is maintaining the withdrawal of these claims. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Claims 61-63 are being withdrawn from consideration since they contain the same subject matter which is in claims 11-13 withdrawn since they are directed at non-elected species.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10, 48-50, 64-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because it is unclear if Applicant is claiming the combination of the "a sheath" and the "device", or the subcombination of the "sheath" alone. This lack of definiteness arises from the clear indication in the preamble that Applicant intends to

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claim only the above subcombination, but Applicant goes on in the claim(s) to positively recite the combination. The claim is considered as having been drawn to the combination. If Applicant indicated by amendment that the combination claim is the intention, the language in the preamble should be made consistent with the language in the body. If indicated that the intent is to claim the subcombination only, the body of the claim must be amended to remove any positive recitation of the combination.

Applicant has only functionally recited the therapeutic material but applicant continues to positively recite the therapeutic material in line 5 of the claim.

Claims 48-50 are vague and indefinite because it is unclear what applicant is intending to claim. The language of "or" makes it unclear whether applicant is intending to claim the sheath to be of a material or to be of a layer in addition to the material of the sheath.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 50-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Khair et al. (U.S. Patent No. 5,425,710).

Khair et al. teach a sheath (14) having a hollow body wherein the body comprises a layer. The Examiner's interpretation of the layer is that it is capable of

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preventing therapeutic material from absorbing due to the inherent property of silicone but applicant has not positively claimed the therapeutic material or the medical device.

As to claims 4-5, Khair et al. teach a coating of Teflon™ (poly(tetrafluoroethylene)). See col. 2, lines 65-68.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 50-54 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Khair et al. (U.S. Patent No. 5,425,710).

Khair et al. disclose a sheath comprising a tubular hollow body for removably covering a balloon catheter. Khair et al. teach the material being coated with a layer of parylene. (see col. 24-44) It is the Examiner's position that parylene inherently encompasses all the parylene species without any further claim limitations. However, in the event that applicant is not convinced, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the parylene of Khair et al. with parylene -C, parylene-D or parylene-N. in order to obtain desired

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properties of the sheath or substitution of materials performing the same function which is to provide environmental barrier protection.

Claims 1-5,9-10, 48-55,59-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khair et al. (U.S. Patent No. 5,425,710) in view of Marotta (Packaging forum).

Khair et al. teach all the limitations of the claims except for the material having a specific oxygen transmission rate or water vapor transmission rate. Khair et al. teach a sheath having with a coating that has the inherent properties of environment barrier protection (see col. 5, lines 39-42.) for shipping and protecting/packaging medical devices. It is further inherent that all materials have a degree of water and/or oxygen transmission rate. Marotta teaches high-barrier plastics such as polyethylene, polypropylene, polystyrene, polycarbonate, nitrile, PVC, polyester, copolyester nylon, PVDC and EVOH for medical devices with specifics of oxygen and water vapor transmission rates in the analogous art of shipping/packaging. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the materials of Khair et al. with the materials as taught by Marotta in order to provide barrier-resistance requirements of medical devices.

Response to Arguments

Applicant's arguments with respect to claims 1-10, have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

Claims 6-8, 56-58, 64-65 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H Thanh whose telephone number is 703-305-0038. The examiner can normally be reached on 5:30 am to 3:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

LoAn H Thanh
Examiner
Art Unit 3763

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LT